



## May 2008 BIOTECH SEMINAR

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**THE NORTH AMERICA TAIWANESE ENGINEERS' ASSOCIATION'S**  
**~SIG BIOTECH~**

### PRESENTATIONS:

**“In Vitro to In Vivo Correlation (IVIVC) –  
Its Significance in Drug Development and A Case Study”**

**DATE:** Friday, May 2nd, 2008

**TIME:** 6:30 PM

**LOCATION:** Squire Sanders Law Firm  
600 Hansen Way, Palo Alto, CA 94304

**REGISTRATION:** FREE for NATEA members, \$5 for non-members, pizza/ soft drink  
RSVP: [ysyang@stanford.edu](mailto:ysyang@stanford.edu) or [slcheng1@yahoo.com](mailto:slcheng1@yahoo.com)

### SPEAKER'S BIO:

Dr Eric Sheu, PhD – Physics (MIT), Vanton Research Laboratory, Inc., Over 20 years of formulation and formulation management experience

- Principal Scientist – Vanton Research Laboratory, Inc. (Concord, CA)
- New pharmaceutical and biotechnology assessment (Lawrence Livermore National Laboratory, Livermore, CA)
- Formulate gel, putty, injectable for controlled and sustained release drug dosage forms (Durect, Cupertino)
- Formulate proteins, oligonucleotides, peptides, nanoparticles/microparticles, emulsions, microemulsions for gene therapy (Genteric, Alameda)
- Formulate drug eluting stent (Guidant, Santa Clara)
- Formulate tablets, pesticides, injectable (Zeneca, Richmond, CA)
- Formulate detergent, cosmetics (night creams, wrinkle cream, sun screen), consumer products, motor oil, fuel, coolants, lubricant (Exxon, NJ; Texaco, NY)

### ABSTRACT:

During drug development process, testing *in vitro* drug release profiles is required to select the lead formulation, even though human clinical trial is the ultimate test of a product. In the pre-clinical stage, *in vitro* drug release rate and *in vivo* animal pharmacokinetics (drug concentration in animal blood as a function of time) are often used to fine-tune the formulation before conducting human

clinical trials. The *in vitro* and *in vivo* release profiles usually differ, and some correlation should be established to “read” the *in vivo* meaning from the *in vitro* data. Once the clinical trials are successfully completed, there is a demand from FDA to ensure each batch produced is consistent with the clinical trial batch. Since it is not possible to perform human clinical trial for every batch, an *in vitro* release rate method should be developed to test the consistency of each batch using the *in vivo* pharmacokinetics of the clinical trial batch as the benchmark. In order to quantitatively evaluate how close the batch mimics the clinical batch, there must be a quantitative correlation between the *in vitro* release rate and the *in vivo* human pharmacokinetics. This correlation is called the *in vitro* to *in vivo* correlation (IVIVC). It is a mathematical relation that transforms the *in vitro* data in to the *in vivo* space to directly reveal the therapeutic meanings. In this presentation, I will briefly describe the FDA requirement on VIVIC, introduce the IVIVC concept using prophetic examples, and finally show a real case to demonstration the criticality of IVIVC in developing a sustained release dosage form.